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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,032	09/11/2003	Christophe Arbogast	57637/1185	6754

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/661,032	ARBOGAST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	D. L. Jones	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 66-75,111 and 113-134 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-70,111,113-122,124-128,131,133 and 134 is/are allowed.
- 6) ☒ Claim(s) 74, 75, 123, 129, and 132 is/are rejected.
- 7) ☒ Claim(s) 71-73 and 130 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 11/4/05 wherein the specification is amended and claims 1-65, 76-110, and 112 are canceled; claims 66, 67, 69, 71, 111, 122, 124, and 125 are amended; and claim 134 was added.

**Note:** Claims 66-75, 111, and 113-134.

## **RESPONSE TO APPLICANT'S ARGUMENTS**

2. The Applicant's arguments filed 11/4/05 to the rejection of claims 66-75, 111, and 113-133 made by the Examiner under 35 USC 112, and/or double patenting have been fully considered and deemed persuasive-in-part.

### **Double Patenting Rejections**

The double patenting rejection is WITHDRAWN.

### **112 First Paragraph Rejections**

The rejection of claims 74 and 75 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is MAINTAINED for reasons of record in the office action mailed 8/1/05 and those set forth below.

Applicant asserts that one would understand which diseases are included in the instant invention and would be able to practice the claimed methods of treating without undue experimentation. In addition, Applicant asserts that the instant specification provides a list of diseases associated with angiogenesis and other diseases that may be treated with the invention.

Applicant's arguments are found non-persuasive. First, as stated in the previous office action, the instant invention encompasses every possible disease that exists (see claim 74). In other words, while claim 75 discloses that the disease is associated with angiogenesis, the claims are not limited to angiogenesis diseases only (as indicated by claim 74). Secondly, a 112, first paragraph, enablement rejection sets forth that the claims contain subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention. Thus, as stated in the previous office action, the instant specification does not describe what diseases are treatable using the compositions of the instant invention. In addition, since the claims that are directed to D32 and D33 compounds are novel, the references of record do not indicate which specific diseases or classes of diseases are treatable with D32 and D33 compounds. Why? Well, if the compounds are novel, then the prior art references would not anticipate or render obvious a method of use for a novel compound. So, the instant invention does not set forth any specific data or other evidence as to which diseases are treatable with D32 and D33. Instead, Applicant has cited US Patent No. 6,025,331 (Moses et al) as disclosing diseases that MAY be treatable. Now, while US Patent No. 6,025,331 disclose numerous diseases, the reference specifically states that the pharmaceutical compositions comprising troponin subunits C, I, and T which inhibit stimulated endothelial cell proliferation. Thus, the characteristics/properties of Moses et al are not necessarily the same as those of Applicant. Hence, for novel compounds, (1) the state of the prior art does not provide the necessary teaching to determine which

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diseases are treatable with Applicant's novel compounds; (2) the level of one of ordinary skill in the art is high especially since art pertaining to diseases and how they respond to various compounds is unpredictable; (3) the guidance provided by Applicant wherein one is referred to a patent belonging to someone else is not sufficient since one the compounds are structurally different, thus, their properties would be different from of the claimed invention. Hence, such guidance does not enable the public to use the compounds of the instant invention due to the lack of guidance set forth in the specification for using the instant compounds. (4) The breadth of the claims would encompass any and all possible diseases. There are no limitations set forth on the conditions being claimed (see claim 74). (5) The instant invention lacks any working examples for which the compounds (i.e., D32 and D33) have been used to diagnosis or treat any disease. As a result, it has been set forth that the claims are not properly enabled.

**112 Second Paragraph Rejections**

I. The rejection of claims 66, 67, 69, 122, 124, 125, 127, and 128 is  
WITHDRAWN.

II. The rejections of claims 123, 129, and 132 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 8/1/05 and those set forth below.

Applicant asserts that the phrase 'polyethylene glycol derivative' is definite because a skilled practitioner would recognize that the phrase refers to compounds that

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are useful as linkers and retain the characteristics of polyethylene glycol that make it useful as a linker for the instant invention. In addition, Applicant asserts that numerous patents have claims that contain the term 'derivative'. Thus, the term is definite.

Applicant's argument is found non-persuasive because the phrase 'polyethylene glycol derivative' is not limited to only compounds that are useful as linkers and retain the characteristics of polyethylene glycol that are useful as linker for the instant invention. Instead, the claim reads on any derivative, active or not. It should be noted that the rejection was withdrawn for claim 119 that has the phrase 'carboxymethyl substituted derivative'. The reason for withdrawing that rejection is that Applicant defined that the derivatives are diethylenetriamine pentaacetic acid or tetrazacyclododecane triacetic acid derivatives which are substituted with a carboxymethyl group. Thus, in that instant Applicant is setting forth the specific group of derivatives that are useable for the instant invention. In other words, Applicant's use of the phrase carboxymethyl derivatives of diethylenetriamine pentaacetic acid or tetrazacyclododecane triacetic acid in the claim is interpreted as compounds that retain the characteristics of diethylenetriamine pentaacetic acid or tetrazacyclododecane triacetic acid since Applicant has set forth the specific derivatives of interest. But, the interpretation of the phrase 'polyethylene glycol derivative' is not afforded the same interpretation since the phrase does not exclude derivatives of polyethylene glycol which do not retain the characteristics of polyethylene glycol. Therefore, the rejection is deemed proper.

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In regards to claim 123 which defines J as a homopolyamide or heteropolyamine derived from synthetic or naturally occurring amino acids is vague and indefinite for reasons of record in the office action mailed 8/1/05. However, Applicant asserts that the phrase is definite and understood to define a group of organic compounds that contain more than one of either the same or different amine groups as well as carbon, nitrogen, or hydrogen, and which are derived from amino acids that are either synthesized or naturally occurring.

Applicant's argument is found non-persuasive because it is unclear which organic compounds containing more than one of either the same or different amine group, as well as carbon, nitrogen, or hydrogen Applicant is claiming to be compatible with the instant invention.

The rejection over claim 129 is maintained because it is unclear whether Applicant intended to add more text since the claims do not contain a period.

### **ALLOWABLE CLAIMS**

3. Claims 66-70, 111, 113-122, 124-128, 131, 133, and 134 are allowable over the prior art of record for reasons of record in the office action mailed 8/1/05.

### **CLAIM OBJECTIONS**

4. Claims 71-73 and 130 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Note:** The claims are distinguished over the prior art of record for reasons of record in the office action mailed 8/1/05.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

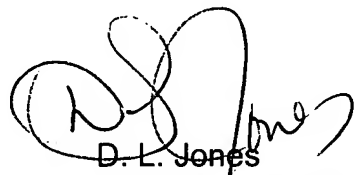


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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

February 6, 2006